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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/606,157	REILLY ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *18,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 8/20/2007.

2. In the reply, the Applicant amended claims 1, 12, 14, and 19. Claims 18, 22, and 23 remain withdrawn.

3. The amendments to the claims obviate the previous objections to the claim 14 and the 35 USC 112(2nd) paragraph rejection of claims 1 and 14.

4. Additionally, the Applicant made the necessary forthcoming statement showing that Trocki et al (6652489) is an not by another. Thus, the 35 USC 102(e) rejections to claims 13 and 19 has been hereby withdrawn.

5. Thus, claims 1-17, 19-21 are pending for examination.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Neer et al (5279569). Neer et al discloses a syringe (Fig 4) for use with an injector comprising a syringe retaining mechanism (Fig 4; col 11, lns 10-40), the syringe

comprising: a body (30) comprising a rearward end and a forward end; a plunger (54) sealing disposed within the body; and at least one attachment member (37, 46; Fig 4) associated with the body, the at least one attachment member comprising a flexible ring (46; col 7, 59-61) operable to releasably attach the syringe to the injector; wherein rotation of the syringe about its axis when attached to the injector causes deformation of the flexible ring to enable detachment of the syringe from the injector (46, col 7, lns 59-61; col 11, lns 10-40; wherein the Examiner notes that the O-ring (46) is fully capable of performing the function of the intended use language by forming a seal between the flange (37) and the jacket (31) securing the syringe in the door (25) and when the syringe is rotated and released, the O-ring's seal is released, allowing the O-ring to return to its normal shape by releasing the pressure exerted thereon by the flange and jacket, thus helping to allow the syringe to be detached from the injector.

8. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Bendek et al (5921966). Bendek et al discloses a syringe (Fig 1) for use with an injector comprising a syringe retaining mechanism (16a, b), the syringe comprising: a body (46, 18) comprising a rearward end and a forward end; a plunger (46b) sealing disposed within the body; and at least one attachment member (18 a, c) associated with the body, the at least one attachment member comprising a flexible ring (18 a, c; Fig 5a; col 4, lns 21-24) operable to releasably attach the syringe to the injector.

9. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Fago et al (6569127). Fago et al discloses an injector (Fig 5-10) for injecting fluid from a syringe mounted thereon, the injector comprising: a housing (48); a drive member (13) at least

partially disposed within the housing and operable to engage a plunger sealing disposed within the syringe; and a syringe retaining mechanism (Fig 8-10, col 8, lns 7-46) associated with the housing and being operable to releasably seat the syringe upon axial rearward motion of the syringe relative to the syringe retaining mechanism regardless of the orientation of syringe about the axis of the syringe (Fig 8-10, col 8, lns 7-46), the syringe retaining mechanism consisting essentially of a flexible ring (90a, b; 92a; col 8, lns 18-24) maintained at a fixed axial position within the syringe retaining mechanism.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-17, 19-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-39, 53 of U.S. Patent No.

6652489. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending parent case. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application and it has been held that the generic invention is anticipated by the species.

12. Claims 1-17, 19-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-21 of Application No. 10/668673. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending parent case. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application and it has been held that the generic invention is anticipated by the species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

13. Applicant's arguments filed 8/20/2007 with respect to claims 1-17, 19-21 have been considered but are not persuasive.

14. The Applicant argues that:

i. Neer does not teach or disclose the claim limitations of having at least one attachment member associated with the body because the syringe (32) is separate from the pressure jacket assembly (30). (Remarks, pg 9-10)

15. In response to the applicant's argument (i), the Examiner notes that "associated with the body" does not necessitate that the at least one attachment member is integral part of the body. The Applicant appears to be taking a more narrow definition of associated with than is present in the claim recitation. In the instant case, the flexible ring (46) is associated with the pressure jacket assembly (30) as shown in Fig 4 and the pressure jacket houses the syringe body (50). Thus, the flexible ring is associated with the body. The Examiner recommends that the Applicant add additional structural definitions to further define the relationship between the attachment member and the syringe body.

> ii. Neer does not disclose a flexible ring that is operable to releasably attach the syringe to the injector. The O-ring (46) does not operate to deform and release the syringe from attachment with the injector upon rotation of the syringe about an axis relative to the injector. (Remarks, pg 10, paragraph 2)

16. In response to the applicant's argument (ii), the Examiner notes that the o-ring (46) is fully capable of performing the function and intended use of the applicant's claims because the o-ring forms a seal between the flange (37) and the jacket (31) securing the syringe (50) in the door (25) and when the syringe is rotated the o-ring's seal is released, allowing the o-ring to return to its normal shape by releasing pressure exerted thereon by the flange and jacket. This results in the syringe being allowed to be detached from the injector. Again, the Applicant appears to be taking a narrower interpretation of the Applicant's claim limitations. It is noted that the features upon

which applicant relies (i.e., the o-ring releasably engaging parts of the syringe) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instance case, there is no requirement present in the claim limitations that the o-ring must contact or engage any portion of the syringe. The rejection is maintained.

> iii. Bendek does not teach a flexible ring attachment member associated with the body that is operable to releasably attach the syringe to the injector. Rather, the members are inflexible and rigid lugs (18a) that are disposed on the cartridge retainer (18) that is not a syringe body. (Remarks, pg 11, paragraph 1)

17. In response to the applicant's arguments (iii), the Examiner notes that there is no recitation present in Bendek that refers to the lugs (18a) on annular projections (18c) as rigid and inflexible. Furthermore, the lugs on the annular projections are fully capable of being bent or flexed to some degree without injury or damage. Thus, they are flexible. The applicant has not recited a limitation that specifies a required degree or the extent of the elements flexibility in the claim. Additionally, as stated above in (i) the current claim limitations do no necessitate or require the attachment mechanism, or the lugs, to be disposed on the syringe body. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The rejection is maintained.

iv. Fago does not teach a syringe retaining mechanism associated with the housing and being operable to releasably seat the syringe upon axial reward motion of the syringe relative to the syringe retaining mechanism .... The syringe retaining mechanism consisting essentially of a flexible ring ..." Rather, the arms (90a,b) of Fago are rigid and not flexible. (Remarks, pg 12, paragraph 4)

18. In response to the applicant's arguments (iv), the Examiner notes that the arms of Fago (90a,b, 92, a, b) are indeed disclosed as being flexible (col 8, lns 18-24). First, Fago explicitly discloses that the arms may have flexible rubber seals (92a,b) on the interior edges of arms (90a, 90b). Second, the arms are disclosed as providing mechanical stability; however, this does not preclude that the arms rigid and inflexible. The applicant has not recited a limitation that specifies a required degree or the extent of the elements flexibility in the claim. The lugs on the annular projections are fully capable of being bent or flexed to some degree without injury or damage. An element can still provide mechanical stability while acting in flexible manner or retaining a degree of flexibility. Thus, they are flexible and read on the applicant's current claim limitations.

19. Additionally, the arms are fully capable of acting to seat the syringe upon axially rearward motion regardless of syringe orientation. For example, the arms are fully capable of being biased open prior or during insertion and then upon rearward motion regardless of syringe motion the arms may be released to form a lock and seat the syringe (see Figs 8-10). The rejection is maintained.

v. The double patenting rejection to Trocki '489 is improper because the claims of Trocki are patentably distinct and structurally very different from the present claimed invention having at least one release member being axially foraward of the at least one attachment member. (Remarks, pg 13, 1.)

20. In response to the applicant's argument (v), the Examiner notes that the metes and bounds of claims 16-39 and 53 of Trocki '489 are merely broader than the copending parent case, claiming similar subject matter, and under the broadest reasonable interpretation presently read on the present claimed invention. For instance, in view of at least claims 16 of Trocki '489 reads thereupon claim 19 of the present application. The Examiner recommends filing a Terminal Disclaimer to overcome the rejection.

vi. The provisional double patenting rejection to 10/6668673 is improper because the claims of the present invention are novel over the claims of 10/66876.

21. In response to the applicant's argument (vi), the Examiner respectfully disagrees and notes that claims 13-21 disclose claims that are similar in scope, subject matter, and merely broader than the copending case. For instance, claims 13-21 disclose at least an injector, a flexible retaining ring being a retaining mechanism, a grooved ring manipulating the flexible ring from relaxed/tensioned states to release the syringe. The similar scope, subject matter, and broadness of the pending claims read upon pending

claims in the present application, such as claim 19. The Examiner recommends filing a Terminal Disclaimer to overcome the rejection.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER